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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,657	10/24/2003	Sylvain Chemtob	GOUD:040US	1182

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,657	CHEMTOB ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-4, as drawn to a method for identifying a non-competitive peptide inhibitor of VEGFR, classified in class 436, subclass 537.

2. Claims 1-3, 5, as drawn to a method for identifying a non-competitive peptide inhibitor of IL-1Rα, classified in class 436, subclass 537.

3. Claims 1-3, 6, as drawn to a method for identifying a non-competitive inhibitor of IL-1Rap, classified in class 436, subclass 537.

4. Claims 1-3, 7, as drawn to a method for identifying a non-competitive peptide inhibitor of IGF-1R, classified in class 436, subclass 537.

5. Claims 1-3, 8, as drawn to a method for identifying a non-competitive peptide inhibitor of IL-4R, classified in class 436, subclass 537.

6. Claims 1-3, 9, as drawn to a method for identifying a non-competitive peptide inhibitor of EGFR, classified in class 436, subclass 537.

7. Claims 1-3, 10, as drawn to a method for identifying a non-competitive peptide inhibitor of GHR, classified in class 436, subclass 537.

8. Claim 11, as drawn to a method for identifying a peptidomimetic, classified in class 436, subclass 537.

9. Claims 12, 13, 18, 23, and 27, as drawn to a peptide antagonist of VEGFR, classified in class 530, subclass 300.

10. Claims 12, 14, 19, 24, 28, as drawn to a peptide antagonist of IL-1Rap, classified in class 530, subclass 300.

11. Claims 12, 15, 20, as drawn to a peptide antagonist of IL-1R, classified in class 530, subclass 30.

12. Claims 12, 16, 21, 25, 29, as drawn to a peptide antagonist of IGF-1R, classified in class 530, subclass 300.

13. Claims 12, 17, 22, 26, 30, as drawn to a peptide antagonist of IL-4R, classified in class 530, subclass 300.

14. Claim 31, as drawn to a method for treating a disease, classified in class 514, subclass 2.

15. Claim 32, as drawn to a pharmaceutical composition for treating a disease, classified in class 514, subclass 2.

16. Claims 33-36, as drawn to a method for identifying a cytokine receptor agonist, classified in class 436, subclass 537.

17. Claim 37, as drawn to a non-competitive cytokine receptor agonist, classified in class 530, subclass 300.

Claims 1-3 and 12 link(s) inventions in groups 1-7 and 9-13, respectively. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3 and 12. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional

statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

B. The inventions are distinct, each from the other because of the following reasons:

1. Inventions 1-8, 14, 16 are independent and distinct inventions, each from the other, because the methods are practiced with materially different process steps for materially different purposes, and each method requires a non-coextensive search because of different starting materials, process steps, and goals. In the instant case, the inventions of groups 1-7 are drawn to methods of identifying peptide inhibitors of different cytokine receptors that are structurally and functionally distinct. Therefore, the structures and composition of the peptide inhibitors are also distinct, as is the biochemical/physiological end-point of the methods. Group 8 is drawn to a method of identifying a peptidomimetic inhibitor of cytokine receptors, and is therefore drawn to identifying a class of inhibitors that is structurally and chemically different than the peptide antagonists of groups 1-7. Group 14 is drawn to a method for treating a disease, and has different process steps and goals. The invention of group 16 is drawn to a method for identifying a cytokine receptor agonist, and thus has different starting materials, process steps, and goals.

2. Inventions 1-8 are unrelated to inventions 9-13, 15, 17. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups 1-8 are drawn to methods of identifying inhibitors of cytokine receptors, and therefore have different modes of operation, different functions, and different effects than the products of groups 9-13, which are drawn to peptides, group 15, which is drawn to a pharmaceutical composition, or group 17, which is drawn to a cytokine receptor agonist.

3. Inventions 9-13, 15, and 17 are independent and distinct inventions, each from the other, because they are products that possess characteristic differences in structure and function, and each has a distinct and independent utility. In the instant case, the inventions of groups 9-13 are drawn to peptide inhibitors of cytokine receptors, which are different in structure and function among themselves, as well as from the invention of group 15, which is a pharmaceutical composition. The invention of group 17 is drawn to a cytokine receptor agonist, and is therefore structurally and functionally distinct from the peptides of groups 9-13, and the pharmaceutical composition of group 15.

4. Inventions 9-13, and 15 are related to invention 14 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of group 14, drawn to a method for treating a disease, can be practiced with another materially different product, such as an antibody.

5. Inventions 9-13, and 15 are unrelated to invention 16. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups 9-13 are drawn to peptide antagonists, and have different functions and effects from the peptide agonists of group 16. Group 15 is drawn to a pharmaceutical composition, and therefore has a different mode of operation, function, and effects from the peptide agonists of group 16.

6. Inventions 14 and 16 are unrelated to invention 17. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating a disease, a method for identifying a cytokine receptor agonist, and a cytokine receptor agonist, and therefore have different modes of operation, function, and effects.

C. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

D. Additionally, groups 1-7 and 9-13, are subject to further restriction. It is noted that the claims are drawn to examination of at least one of a number of structurally distinct and non-overlapping peptide fragments. **In order to be fully responsive**, applicant is required to further restrict a specific combination of peptides. This is NOT an election of species. The claimed peptide fragments are non-overlapping sequences and are structurally distinct chemical compounds, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such peptide is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Claims 4-10, 13-17, and 23-30 are generic to a plurality of disclosed patentably distinct amino acid residues (claims 4-10 and 13-17), and separate and distinct amino acid sequences (claims 23-30). Should Applicant elect from Groups 1-7, Applicant is required to elect a single peptide. For example, if Group 1 is elected, Applicant must further elect from:

a) residues 320-350
b) residues 350-400
c) residues 400-440
d) residues 481-565
e) residues 640-685
f) residues 745-770

Similarly, Applicant's elect from Groups 9-13, Applicants are required to elect a single amino acid sequence from claims 13-17, and a single amino acid sequence from claims 23-30. For example, if Group 9 is elected, Applicant must further elect a peptide selected from claim 13:

a) residues 320-350
b) residues 350-400

c) residues 400-440

d) residues 481-565

e) residues 640-685

f) residues 745-770

and a single sequence selected from claim 23:

a) SEQ ID NO:1

b) SEQ ID NO:2

c) SEQ ID NO:3

and a single sequence selected from claim 27:

a) SEQ ID NO:1

b) SEQ ID NO:2

c) SEQ ID NO:3

E. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

F. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

G. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached on 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
Art Unit 1646

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PRIMARY EXAMINER